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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/760,100

01/16/2004

Jonathan C. Heller

29191-707.501

7363

21971 7590 02/01/2007  
WILSON SONSINI GOODRICH & ROSATI  
650 PAGE MILL ROAD  
PALO ALTO, CA 94304-1050

EXAMINER

AGRAWAL, RITESH

ART UNIT

PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/760,100

Applicant(s)

HELLER ET AL.

Examiner

Ritesh Agrawal

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 25-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-24 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :01/16/04, 07/07/04, 09/23/04, 11/15/04, 03/01/05, 06/17/05, and 09/30/05.

## **DETAILED ACTION**

### ***Election/Amendments***

1. Applicant's election without traverse of Group III (claims 17-24) in the reply filed on 01/05/07 is acknowledged.

Claims 1-16 and 25-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/05/07.

### ***Information Disclosure Statement***

2. The Information Disclosure Statements filed 01/16/04, 07/07/04, 09/23/04, 11/15/04, 03/11/05, 06/17/05, and 09/30/05 have been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

### ***Drawings***

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are not in compliance with 37 CFR 1.84 (t). The drawings do not provide for sheet numbers. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Specification***

4. The disclosure is objected to because of the following:

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because the elected invention is specifically drawn to a system comprising a microfluidic device, however there is no mention of such a device in the abstract. The abstract is more generally drawn to methods and systems for customization. Correction is required. See MPEP § 608.01(b).

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The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The title is drawn to assay customization, however the elected invention is specifically drawn to a system comprising a microfluidic device.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites a system that is "used to separate a disease state" in lines 1-2. It is unclear as to what the disease state is to be separated from (another disease state, a wildtype state, or is there to be separation within members of the disease state).

### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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6. Claims 17-24 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Andersson et al. (Patent Publication # 2002/0142481) with a publication date of October 3<sup>rd</sup>, 2002 and a filing date of March 19<sup>th</sup>, 2001.

The claims are drawn to a system comprising a microfluidic device comprising a separation section, an electrospray section, the microfluidic device being disposable, and a mass spectrometer coupled to the microfluidic device.

Andersson et al. disclose a system comprising a microfluidic device interfaced to a mass spectrometer (paragraph 1, lines 1-2). They disclose that the microfluidic device comprises a separation section (paragraph 94, lines 1-2). Furthermore, they disclose the microfluidic device may comprise an electrospray section (paragraph 97, lines 10-11) and that the microfluidic device may be disposable (paragraph 29, lines 1-2).

With respect to claim 18, Andersson et al. disclose that the mass spectrometer may be a time of flight mass spectrometer (paragraph 120, lines 1-4).

With respect to claim 20, Andersson et al. disclose that the microfluidic device can be decoupled from the mass spectrometer and covered using a lid (paragraph 50, lines 1-6).

With respect to claim 22, Andersson et al. disclose that the microfluidic device can comprise a capillary electrophoresis device (paragraph 78, lines 1-4).

With respect to claim 23, Andersson et al. disclose the use of soluble (paragraph 85, line 32) beads (paragraph 85, lines 20-21) for separation.

With respect to claim 24, Andersson et al. disclose the use of reverse phase chromatography (paragraph 93, line 4).

With respect to claims 19 and 21, they additionally limit the system of claim 17 by methods of use. Since the claims are drawn to the product itself, Andersson et al.'s disclosure of the product of claim 17 sufficiently discloses the claimed inventions (see MPEP 2113).

### ***Claim Objections***

7. Claim 24 is objected to because of the following informalities: Claim 24 recites the phrase "said microfluidics device comprises reverse phase chromatography device" in lines 1-2. It appears that there is a missing "a" between "comprises" and "reverse." Appropriate correction is required.

### ***Conclusion***

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ritesh Agrawal whose telephone number is (571) 272-2906. The examiner can normally be reached on 8:30 AM - 5:00 PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ritesh Agrawal, PhD



SHUBO (JOE) ZHOU, PH.D.  
PATENT EXAMINER